

1. AMENDMENT OF SOLICIATION: NIMH-00-DS-0004
2. AMENDMENT NO.: ONE (1)
3. EFFECTIVE DATE: May 15, 2000
4. ISSUED BY: National Institute of Mental Health, (NIMH)
Contracts Management Branch, ORM
6001 Executive Boulevard
Room 6107, MSC 9603
Bethesda, Maryland 20892-9603
5. NAME AND ADDRESS OF CONTRACTOR: To all Offerors
6. NIMH POINT OF CONTACT: Robert D. Barnie
(301)443-4116
rb245s@nih.gov
7. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICIATIONS: The above numbered solicitation is amended as set forth in Item 8 below. The hour and date specified of offerors is NOT extended, thus proposal due date remains Monday, July 24, 2000, at 3:30 PM, EASTERN PREVAILING TIME.
8. DESCRIPTION OF AMENDMENT: The purpose of this modification is to answer questions and provide clarifications to the subject Request for Proposal.

QUESTIONS AND ANSWERS

On page 6 of the RFP under 3. General Requirements, it suggests that "All work shall be conducted in coordination with the other clinical sites making up the MTA Group (which shall operate as a research network) and in conjunction with the Data Management Center." Because this contract will no longer be a cooperative, could:

Q.1.A. One of the MTA sites take on the responsibility of functioning like a coordinating center?

A.1.A. The NIMH is looking to the MTA Group to propose a technical approach that will result in the best end product while minimizing costs. The NIMH does not expect the need for a coordinating "center" for this follow-up study and the data management function is not included in the scope of work and should not be considered when preparing technical and business proposals. However if the sites jointly agree, that it is advantageous from both a technical and cost perspective, then one site may be selected to perform coordinating function tasks. Coordinating function tasks could include facilitating communications among the sites, ensuring that appropriate consultants are identified and utilized for the purposes of conducting the work outlined in the statement of work and integrating input from the sites, especially when written reports need to be prepared in a timely fashion.

Q.1.B. The contract be made to that single coordinating site, with subcontracts to the others, like the TADS contract?

A.1.B. See response to Question 1.A.

Q.1.C. The coordinating site be the Data Center?

A.1.C. No, the functions of the Data Management Center are not a part of this requirement and should not be included as part of the technical or cost proposals submitted in response to this RFP.

Q.1.D. The Data Center handle all reports to NIMH, send data to the DSMB, arrange conference calls and meetings, carry out forms generation and tracking, but leave all scientific decisions to the MTA Steering Committee?

A.1.D. As indicated in the answer to question 1.C., the duties of the Data Management Center are not included in this requirement.

Q.1.E. Also, will each site be submitting a technical report for that site, even though it will resemble the other technical reports in the Statement of Work?

A.1.E. It is not clear what is meant by "technical report". However, if separate contracts are awarded to each site, then each site will be required to submit its own progress reports outlining the activities that have taken place at that site for the reporting period. Such information as the number of families interviewed, number of forms completed, retention rates, etc. will need to be included in these progress reports.

Q.2. On page 8, Under "Meetings/Communications" f.3, it states that the "Contractor shall plan to attend approximately one meeting a year, as deemed necessary by the GPO." Is this meeting only a MTA Network Meeting, or does this include travel funds for professional meetings, where MTA results could be presented?

A.2. It is envisioned that the meeting will be an MTA Network Meeting; however at the discretion of the GPO and in collaboration with the MTA Group members, the travel funds may be utilized for professional meetings, where MTA results could be presented.

Q.3. Am I correct in assuming that on page 17, under "4. Technical Evaluation Criteria," that "Personnel and Management Plan" and the "Facilities, Equipment and Resources," are different for each site?

A.3. See response to Question 10.

Q.4. On page 33, item (17) Institutional Responsibility Regarding Conflicting Interests of Investigators," it states that we must "maintain an appropriate written, enforced policy on conflict of interest. ...[and] ..designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in

NIH-funded research." Do we need to have a form or a statement included in the Technical Report describing each site's local arrangement for this function?

A.4. See response to Question 10.

Q.5. On page 37, the instructions for the technical report requests that "Offerors should assure that the principal investigator, and all other personnel proposed, shall not be committed on federal grants and contracts for more than a total of 100% of their time...". It also asks for "the name of the Principal Investigator/Project Director...Other Investigators...Additional Personnel..(on page 38) ..resumes...Facilities and Resources." This section will be individualized for each site, rather than being identical in terms of FTE's?

A.5. See response to Question 10.

Q. 6. The cohorts of MTA Children were recruited in 3 different years. Also, Pittsburgh and Columbia recruited uneven cohorts - 25 in year 1 and 71 in year 2. Can there be a staggered work schedule in order to assess each subject at a uniform time after the Treatment or at a uniform age?

A.7. As indicated in the answer to question 1.A., the NIMH is looking to the MTA Group to propose in a manner that will result in the best end product while keeping costs to a minimum. If that can best be accomplished by staggering the work schedule in order to assess each subject in a uniform time after treatment or at a uniform age, then it is acceptable to the NIMH to propose in that manner.

Q.8. Where should we assign the costs for things that are an expense for the study as whole, not site-specific, such as the statistical consultant, SC executive secretary, Peter Jensen, and teleconferences? Will they be assigned to NIMH contracts office or to one of the sites?

A.8. As indicated in the answer to question 1.A, these costs may be charged to one site if that is both a technically and cost efficient approach.

Q.9. Can teleconferences for the Steering Committee be arranged to run for free on FTS (like the RUPP) or do we need to budget costs at AT&T? (Scheduling them for FTS will save a considerable amount of money).

A.9. It is anticipated that the need of network telephone conference calls will be limited and not comparable to those associated with the Cooperative Agreements that supported the actual treatment study. For proposal purposes, assume that the NIMH will initiate and pay the costs associated with half of the necessary network telephone conference calls.

Q.10. Please confirm that you only want to receive ONE technical proposal and ONE business proposal by July 24, 2000. If this is true, do we put all the site-specific assurances, certificates, resources, facilities, resumes for all the sites into ONE business proposal? Or

do we put NO site-specific information in either proposal and just wait for the "just-in-time" requests if the technical proposal is approved? This would be VERY different from the RFP instructions. If not, how will the peer review group evaluate the feasibility of our proposal if we don't include site-specific resumes, descriptions of resources and facilities?

- A.10. The NIMH is looking for one technical proposal from the MTA Group that contains limited site-specific information, such as resumes and brief descriptions of resources and facilities.

In an effort to minimize the time and costs related to the submission of proposals, the NIMH is requesting that the MTA Group submit only one cost proposal with its original submission (as opposed to a separate cost proposal from each site). This cost proposal should reflect the composite costs of the MTA Group to complete the entire study. The NIMH envisions that this will require the MTA Group to work in concert to maximize the technical aspects of the proposal while minimizing costs. NIMH's Final Proposal Revision letter will request each site to submit its documents required by the "JUST IN TIME" paragraph of the RFP that are unique to each site (refer to paragraph A on page 19 of the RFP) and are necessary to make an award to the site. In addition, each offeror shall submit, as part of its "JUST IN TIME" submission, site specific budgets, Representations, Certifications, and Other Statements of Offerors or Quoters and Disclosure of Lobbying Activities.